

### REMARKS/ARGUMENTS

The foregoing amendments and these remarks are responsive to the non-final Office Action mailed April 10, 2007. Applicant submits that Applicant's pending claims are patentable over the references of record, and requests reconsideration and allowance.

In the Office Action, Claims 26-33 and 35-39 were rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich, U.S. Pat. No. 5,409,488 ("Ulrich"). Claim 34 was rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich in view of Taylor U.S. Pat. No. 6,685,705 ("Taylor").

The Examiner has cited the following sections of Ulrich as disclosing or suggesting Applicant's invention: Col. 1, lines 50-70 and Col. 2, lines 22-27, and Col. 3, lines 10-20. These sections are reproduced below to facilitate review. Applicant's invention is directed to a new, previously undiscovered method of repairing the facet joints, one of dynamic stabilization. In the method of the invention, a spinal implant rod and at least one fixation connector assembly and at least one sliding connector assembly are used. Each connector assembly comprises a post and a connecting member having a rod connecting portion and a post connecting portion. The sliding connector assembly has a rod connecting portion with structure for slidable engagement of the rod, and the fixation connector assembly has a rod connecting portion with structure for engaging the rod so as to prevent sliding movement of the rod relative to the fixation connector assembly. The post of the sliding connector assembly or the fixation connector assembly is positioned and secured in the area of the superior articular facet of a lower vertebrae. The post of the other of the sliding connector assembly or the fixation connector assembly is positioned

{WP408321;1}

and secured in the area of an inferior articular facet of an adjacent upper vertebrae. **By the phrase "in the area," it is meant that the posts are positioned generally at or between the location of the facets of the patient, however, it should be understood that the precise location will be determined by the physician in order to best address the condition of the patient.** The rod is then secured to the sliding connector assembly so as to permit slidable movement relative thereto postoperatively, and is secured to the fixation connector assembly so as to prevent slidable movement relative thereto postoperatively.

Applicant submits that careful examination of the cited sections reproduced above will reveal that Applicant's invention is not anticipated or rendered obvious by these sections. The first cited section, at Col. 1, is as follows:

According to the invention an implant provides between the two connection pieces a further connection also equipped with a receiving element for a resetting screw, whereby on this median connection piece the threaded spindles for the two outer connection pieces are supported so that they are independently rotatable and axially nondisplaceable. The two threaded spindles are inclined with respect to each other in the common plane of their axes thereby adjusting the implant to the sagittal curvature of the spinal column. Preferably the mutual inclination of the threaded spindles is of approximately 15°.

When such implant is affixed with each of its connection pieces to one of three successive vertebrae, by rotating the threaded spindles, the two outer vertebrae can be independently set and fixated with respect to the middle vertebra mutual inclination of the two threaded spindles takes into account to follow the natural curvature....  
[Col. 1, lines 50-70, emphasis supplied]

Ulrich in this section describes a method in which threaded spindles are used to connect between a median connection piece and two outer connection pieces. The two outer connection pieces are axially nondisplaceable, and therefore not capable of postoperative sliding movement

as required by Applicant's independent claims 26 and 39. The two outer vertebrae are set and fixated, which is opposite to the claimed invention which is directed to postoperative sliding, or dynamic, movement. As seen in Figs. 4-5 of Ulrich, an annular groove 33 on the spindles 1 receives a cross pin 34 to secure the spindles 1 against axial displacement relative to the median connection piece 2'. Accordingly, the Ulrich method is one of postoperative fixation, which is both consistent with the prior art and entirely opposite to Applicant's invention.

The next cited section of Ulrich, at Col. 2, describes only the screw:

...setting screw with a smooth shaft segment succeeding the threaded shaft portion will be used within the framework of the invention, since, after being screwed into the respective vertebra, it can still be shortened to the length desired for the fastening of the connection pieces. [Col. 2, lines 22-27]

This feature is of course well known in the art, and this section of Ulrich adds nothing to disclose or suggest the dynamic facet stabilization method of the invention.

The remaining cited section of Ulrich, at Col. 3, describes the operation of the Ulrich device:

FIGS. 1 and 2 show the spondylodesis implant wherein on threaded spindles 1 and connection pieces 2 are guided, which are adjustable as to their distance from each other by rotating the threaded spindles 1. Altogether three connection pieces 2, 2" are provided, whereby the middle connection piece serves for the support of the two lateral connection pieces so that they are independently rotatable and axially nondisplaceable. Thereby the two threaded spindles 1 are inclined with respect to each other at an angle 30 of approximately 15° in the common plane of their axes, which corresponds with the plane of the drawing...[Col. 3, lines 10-20, emphasis supplied]

The spindles 1 must be rotated in order to adjust the distance from each other. As rotation is not possible post operatively, the spindles and connection pieces are not capable of postoperative sliding movement as in the present invention. Again Ulrich describes the connection pieces 2 as axially nondisplaceable. The median connection piece 2' as discussed above is secured by cross pins 34 to the spindles 1, so this piece is also axially nondisplaceable relative to the spindles 1.

Applicant submits that the pending claims describe a method which is distinguishable from all of the references of record, and particularly the method illustrated by Ulrich. As noted previously, the facet joints generally are hinge-like and allow limited flexion, extension, and twisting motion, while preventing excessive motion which could damage the spinal chord. Spinal reconstructive or treatment procedures which require the removal of the facet joint and ligament structures currently fixate this joint and decrease the mobility and comfort of the patient. Ulrich, although not specifically directed to a facet replacement method, is nonetheless directed to such a fixation device and method.

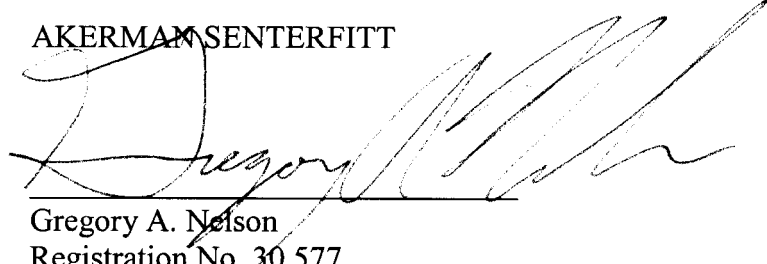
The present invention provides a replacement joint with both strength and stability, and closely resembles the flexibility and range of motion of the natural facet joint. The invention is an effective solution to the problem of reconstructing and replacing the facet in a manner that permits the required stability and mobility of an effective prosthetic device. Ulrich fails to disclose or suggest to one skilled in the art such a method, and is in fact opposite in large part to the dynamic stabilization method of the invention in which postoperative sliding movement is an important feature of the method. Applicant accordingly requests reconsideration and allowance

In re: Application of SIMONSON, Peter M.  
Confirmation No: 6218  
Application No.: 10/720,659  
Examiner: SWIGER, III, James L.  
Page-10-

of Applicant's pending claims. The Examiner is cordially invited to call the undersigned if clarification is needed on any matter within this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

AKERMAN SENTERFITT

A handwritten signature in black ink, appearing to read "Gregory A. Nelson", is written over a horizontal line. The signature is fluid and cursive.

Date: July 6, 2007

Gregory A. Nelson  
Registration No. 30,577  
P.O. Box 3188  
West Palm Beach, FL 33402-3188  
Tel: 561-653-5000